NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC) GUIDELINE SYNTHESIS

OTITIS MEDIA WITH EFFUSION

Guidelines

1. American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery, American Academy of Pediatrics (AAFP/AAOHNS/AAP). Otitis media with effusion. Pediatrics 2004 May;113(5):1412-29. [172 references]
2. Cincinnati Children's Hospital Medical Center. (CCHMC). Evidence based clinical practice guideline for medical management of otitis media with effusion in children 2 months to 13 years of age. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2004 Oct.; 11 p. [67 references]
3. Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of childhood otitis media in primary care. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Feb. 18 p. (SIGN publication; no. 66). [77 references]

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INTRODUCTION

A direct comparison of the American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery, American Academy of Pediatrics (AAFP/AAOHNS/AAP), Cincinnati Children's Hospital Medical Center (CCHMC) and Scottish Intercollegiate Guidelines Network (SIGN)

recommendations for the diagnosis, treatment, and management of otitis media with effusion (OME) is provided in the tables below.

The guidelines differ somewhat in scope. The SIGN guideline addresses diagnosis and management of both acute otitis media (AOM) and OME. AOM is addressed in a separate synthesis. All three guidelines focus on the pediatric population; AAFP/AAOHNS/AAP and CCHMC target children 2 months and older. SIGN does not specify an age range but targets children in general. All three guidelines address clinical assessment and treatment of OME (including drug therapy and management of children at risk for hearing, speech, language, and developmental problems), as well as appropriate referral to audiologists, speech-language pathologists, and otolaryngologists. AAFP/AAOHNS/AAP and CCHMC also address when to consider insertion of pressure equalizing (PE) tubes, while SIGN explicitly excludes this topic. AAFP/AAOHNS/AAP also addresses research needs related to OME. In formulating their recommendations, CCHMC reviewed the conclusions drawn by AAFP/AAOHNS/AAP.

Table 1 compares the scope of each of the guidelines. Table 2 compares recommendations for diagnosis, evaluation, and management of OME in children. Table 3 compares the potential benefits and harms associated with the implementation of each guideline.

Definitions for the levels of evidence used to support the guideline recommendations are given in Table 4; references supporting selected recommendations of the CCHMC guideline are also provided in this table.

Following the content comparison tables, the areas of agreement and differences among the guidelines are identified.

Abbreviations

- AAFP, American Academy of Family Physicians
- AAOHNS, American Academy of Otolaryngology-Head and Neck Surgery
- AAP, American Academy of Pediatrics
- AOM, acute otitis media
- CAM, complementary and alternative medicine
- CCHMC, Cincinnati Children's Hospital Medical Center
- GP, general practitioner
- MEE, middle ear effusion
- OM, otitis media
- OME, otitis media with effusion
- PE, pressure equalizing, pressure equalization
- SIGN, Scottish Intercollegiate Guidelines Network

TABLE 1: COMPARISON OF SCOPE AND CONTENT
Objective and Scope

AAFP/AAOHNS/AAP (2004)	To inform clinicians of evidence-based methods to identify, monitor, and manage OME in children aged 2 months through 12 years
CCHMC (2004)	• To improve the identification of the at-risk child • To improve the use of appropriate referral criteria • To improve parental involvement in decision-making around the management of OME
SIGN (2003)	• To provide recommendations based on current evidence for best practice in the management of AOM and OME • To provide evidence about detection, management, referral, and follow-up of children with AOM and OME **Notes** • This guideline excludes discussion of surgical management such as the insertion of grommets (PE tubes) and does not address issues beyond childhood years. In addition, the needs of children with genetic or facial abnormalities are not considered. • Recommendations for AOM are considered in a separate synthesis.
Target Population	
AAFP/AAOHNS/AAP (2004)	• United States • Children aged 2 months through 12 years with or without developmental disabilities or underlying conditions that predispose to OME and its sequelae **Note**: The guideline may not apply to children more than 12 years old, because OME is uncommon and the natural history is likely to differ from younger children who experience rapid developmental change.
CCHMC (2004)	• United States • Children age 2 months up to 13 years of age who present with signs and symptoms of OME **Note**: Children with functioning pressure equalization (PE) tubes in place are excluded.
SIGN (2003)	• Scotland • Children with AOM or OME **Note**: The needs of children with genetic or facial abnormalities are

	not considered.
Intended Users	
AAFP/AAOHNS/AAP (2004)	Advanced Practice Nurses Nurses Physician Assistants Physicians Speech-Language Pathologists
CCHMC (2004)	Advanced Practice Nurses Allied Health Personnel Health Care Providers Nurses Patients Physician Assistants Physicians Speech-Language Pathologists
SIGN (2003)	Advanced Practice Nurses Nurses Patients Physician Assistants Physicians Public Health Departments Social Workers Speech-Language Pathologists
Interventions And Practices Considered	
AAFP/AAOHNS/AAP (2004)	**Diagnosis/Evaluation** 1. History and physical examination, including documentation of laterality, duration of effusion, and presence and severity of associated symptoms 2. Diagnostic testing: • Pneumatic otoscopy • Tympanometry 3. Risk assessment of children with OME for speech, language, and learning problems, and early intervention **Treatment/Management** 1. Watchful waiting in children with OME who are not at risk 2. Hearing and language testing as needed 3. Surveillance/re-examination of children who are not at risk at 3- to 6-month intervals 4. Referral to a specialist

	5. Surgery, including tympanostomy tube insertion, adenoidectomy, repeat surgery (adenoidectomy plus myringotomy with or without tube insertion) *Considered but recommended against*: • Population-based screening • Drug therapy (antibiotics, antihistamines, decongestants, and corticosteroids) • Tonsillectomy alone or myringotomy alone for the treatment of OME *Considered but no recommendations offered*: • Complementary and alternative medicines (CAM) • Allergy management
CCHMC (2004)	**Diagnosis/Evaluation** 1. History and physical examination, including documentation of laterality, duration of effusion, and presence and severity of associated symptoms 2. Diagnostic testing: • Pneumatic otoscopy • Tympanometry • Acoustic reflectometry 3. Risk assessment of children with OME for speech, language, and learning problems, and early intervention **Treatment/Management** 1. Observation without antibiotics 2. Analgesia 3. Aggressive individualized management of children at risk for developmental difficulties, including early referrals for audiologic evaluation, frequent follow-up, antibiotic therapy, speech/language assessment, PE tubes, and/or other otolaryngological evaluation 4. Follow-up evaluation of the otherwise healthy child with OME **Referral** 1. Referral for audiologic, speech, and language evaluation 2. Referral for otolaryngological evaluation 3. Referral for evaluation for PE tube insertion 4. Appropriate documentation when referring children

	for evaluation by a specialist *Considered but not specifically recommended*: • Antibiotic therapy (not routinely recommended) • Systemic steroids, antihistamines, decongestants, and complementary or alternative treatments **Note**: The guideline also includes recommendations regarding the natural course of OME and follow-up for unresolved OME, preventable risk factors for OME, and prevention of speech or language delay.
SIGN (2003)	**Diagnosis/Evaluation** 1. History and physical examination 2. Diagnostic testing: • Otoscopy (with or without tuning fork) • Pneumatic otoscopy (not typically used in primary care) • Tympanometry 3. Audiometry for hearing thresholds and middle ear function **Treatment/Management** 1. Watchful waiting 2. Autoinflation **Note**: Surgical management is not considered in this guideline. **Referral** 1. Referral for audiometry 2. Referral to an otolaryngologist *Considered but recommended against*: • Antibiotic treatment • Decongestants, antihistamines, mucolytics • Steroids *Considered but no recommendations offered*: • Homeopathy **Note**: This guideline also addresses diagnosis and treatment of AOM (see related synthesis). Additionally, it includes information for parents, teachers, and caregivers and advice about risk factors.

TABLE 2: COMPARISON OF RECOMMENDATIONS FOR DIAGNOSIS, TREATMENT AND MANAGEMENT OF OTITIS MEDIA WITH EFFUSION	
Definition Of OME	
AAFP/AAOHNS/AAP (2004)	OME is defined as the presence of fluid in the middle ear without signs or symptoms of acute ear infection.
CCHMC (2004)	OME is defined as the presence of fluid in the middle ear without signs or symptoms of acute otitis media. More specifically: • OME: MEE without signs or symptoms of infection • Chronic OME: OME with duration more than 3 months
SIGN (2003)	OME is defined as inflammation of the middle ear, accompanied by the accumulation of fluid in the middle ear cleft without the symptoms and signs of acute inflammation. OME is often asymptomatic and earache is relatively uncommon.
Diagnosis And Evaluation	
AAFP/AAOHNS/AAP (2004)	• **Pneumatic Otoscopy**: Clinicians should use pneumatic otoscopy as the primary diagnostic method for OME, and OME should be distinguished from AOM. (This is a strong recommendation based on systematic review of cohort studies and the preponderance of benefit over harm). *Aggregate evidence quality: **A**, diagnostic studies in relevant populations* *Policy level: **strong recommendation*** Non-pneumatic otoscopy is not advised for primary diagnosis. • **Tympanometry**: Tympanometry can be used to confirm the diagnosis of OME. (This option is based on cohort studies and a balance of benefit and harm.) *Aggregate evidence quality: **B**, diagnostic studies with minor limitations* *Policy level: **option*** • **Documentation**: Clinicians should document the

	laterality, duration of effusion, and presence and severity of associated symptoms at each assessment of the child with OME. (This recommendation is based on observational studies and strong preponderance of benefit over harm.) *Aggregate evidence quality: **C**, observational studies* *Policy level: **recommendation***

CCHMC (2004)	**General**
	
	Signs and symptoms of OME are often only identified upon follow-up to AOM or at an unrelated office visit.
	
	History and Physical Examination
	
	• It is recommended that a focused history and physical of the child with OME includes assessment and documentation of:
	  • Intermittent ear pain, fullness, or popping
	  • Hearing/speech concerns (Roberts, Rosenfeld, & Zeisel, 2004 [M])
	  • Balance (Golz, Angel-Yeger, & Parush, 1998 [C]; Casselbrant et al., 1995 [C])
	  • Bilaterality
	  • Duration of effusion
	  • Recurrent AOM
	  • Presence of any craniofacial anomalies (AAFP/AAOHNS/AAP, 2004 [S])
	• It is recommended that OME be diagnosed by the presence of MEE, as assessed by pneumatic otoscopy, without signs and symptoms of acute inflammation (AAFP/AAOHNS/AAP, 2004 [S]).
	
	Note: Adequate illumination for OME diagnosis requires appropriate maintenance of pneumatic otoscopes in the office, including changing the light bulb and battery (Barriga, Schwartz, & Hayden, 1986 [O]).
	
	• It is recommended that tympanometry may be used to enhance accuracy when diagnosing OME (Karma et al., 1989 [D]; Shekelle et al., 2003 [S]; Brookhouser, 1998 [S]; Jones and Kaleida, 2003 [O]; Pichichero, 2002 [O]; Pichichero & Poole, 2001 [O]).
	
	Note: Acoustic reflectometry is not often used nor

	readily available in the Cincinnati area, though the procedure is acceptable for determining the presence of MEE (Block et al., 1999 [C]; Barnett et al., 1998 [C]; Block et al., 1998 [C]; Kimball, 1998 [S]).
SIGN (2003)	**Presentation Patterns For Children with OME** **B** - Healthcare professionals should have an increased awareness of the possibility of the presence of OME in asymptomatic children. The following groups of children are at particular risk: • Those in day care • Those with older siblings • Those with parents who smoke • Those who present with hearing or behavioural problems **Diagnosis of OME** In many studies OME is diagnosed if there is MEE on pneumatic otoscopy with no signs of acute inflammation. In practice, pneumatic otoscopy is not used in primary care. No evidence based studies were identified concerning the most commonly used primary care diagnostic tool--otoscopy (with or without tuning fork testing). Evidence of MEE consists of the presence of either: • At least two tympanic membrane abnormalities (abnormal colour such as yellow, amber, or blue; opacification other than due to scarring; and decreased or absent mobility) and/or • Otoscopy typically showing a retracted/concave tympanic membrane with a colour change (typically yellow or amber). Air bubbles or an air/fluid level may be present and, while not typical, fullness or bulging may be visualized. Pneumo-otoscopy will demonstrate reduced or absent mobility. The main symptom associated with OME is hearing loss (see Table 1 in the original guideline document for additional diagnostic features of OME compared to AOM). However this hearing loss is often not identified in infants and young children. • In most situations, the GP will have to depend on history and otoscopy for diagnosing otitis media.

	(Point of best clinical practice) **Tympanometry** Tympanometry is a very useful tool for diagnosis but is rarely used in the primary care setting in the United Kingdom. • Children who require hearing loss assessment should be referred to an audiologist. (Point of best clinical practice)
Children At Risk For Speech, Language, Or Learning Problems	
AAFP/AAOHNS/AAP (2004)	**Child at Risk**: Clinicians should distinguish the child with OME who is at risk for speech, language, or learning problems from other children with OME and should evaluate hearing, speech, language, and need for intervention more promptly. (This recommendation is based on case series, the preponderance of benefit over harm, and ethical limitations in studying children with OME who are at risk.) *Aggregate evidence quality: **C**, observational studies of children at risk; **D**, expert opinion on the ability of prompt assessment and management to alter outcomes* *Policy level: **recommendation***
CCHMC (2004)	It is recommended that the child with OME who is at risk for developmental difficulties be identified early. These children include those with sensory, physical, cognitive, or behavioral factors listed below (AAFP/AAOHNS/AAP, 2004 [S]). Note: Children with Down syndrome (Shott, Joseph, & Heithaus, 2001 [C]; Whiteman, Simpson, & Compton, 1986 [C]), cranial facial dysostosis (Corey, Caldarelli, & Gould, 1987 [C]), cleft palate (Paradise & Bluestone, 1974 [C]), and autism (Rosenhall et al., 1999 [C]) have been shown to be at higher risk for OME and/or its associated outcomes of developmental delay in hearing, speech, or language. **Risk Factors for Developmental Difficulties** (AAFP/AAOHNS/AAP, 2004 [S]) • Permanent hearing loss independent of OME • Suspected or diagnosed speech and language delay

	or disorder • Autism-spectrum disorder and other pervasive developmental disorders • Syndromes (e.g., Down) or craniofacial disorders that include cognitive, speech, and language delays • Blindness or uncorrectable visual impairment • Cleft palate with or without associated syndrome • Developmental delay
SIGN (2003)	No specific recommendation offered. However in the narrative discussion pertaining to history taking, the guideline developer notes that a relevant element to be elicited in the history includes information about disability in terms of hearing difficulty, together with information on social interaction, behaviour, function in the educational setting and speech and language development.
Non-Surgical Treatment And Management	
AAFP/AAOHNS/AAP (2004)	• **Watchful Waiting**: Clinicians should manage the child with OME who is not at risk with watchful waiting for 3 months from the date of effusion onset (if known) or diagnosis (if onset is unknown). (This recommendation is based on systematic review of cohort studies and the preponderance of benefit over harm.) *Aggregate evidence quality: **B**, systematic review of cohort studies* *Policy level: **recommendation*** • **Medication**: Antihistamines and decongestants are ineffective for OME and are not recommended for treatment; antimicrobials and corticosteroids do not have long-term efficacy and are not recommended for routine management. (This recommendation is based on systematic review of randomized, controlled trials and the preponderance of harm over benefit.) *Aggregate evidence quality: **A**, systematic review of well-designed, randomized, controlled trials* *Policy level: **recommendation against*** • **Surveillance**: Children with persistent OME who are not at risk should be reexamined at 3- to 6-month intervals until the effusion is no longer present,

	significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected. (This recommendation is based on randomized, controlled trials and observational studies with a preponderance of benefit over harm.) *Aggregate evidence quality: **C**, observational studies and some randomized trials* *Policy level: **recommendation*** • **CAM**: No recommendation is made regarding CAM as a treatment for OME. (There is no recommendation based on lack of scientific evidence documenting efficacy and an uncertain balance of harm and benefit.) *Aggregate evidence quality: **D**, case series without controls* *Policy level: **no recommendation*** • **Allergy Management**: No recommendation is made regarding allergy management as a treatment for OME. (There is no recommendation based on insufficient evidence of therapeutic efficacy or a causal relationship between allergy and OME.) *Aggregate evidence quality: **D**, case series without controls* *Policy level: **no recommendation***
CCHMC (2004)	The foundation of OME management is follow-up and monitoring of the presence or resolution of effusion. This monitoring is clinically important for the early identification of the child at risk for developmental difficulties and for the appropriate timing for referral of the child with persistent OME. • It is recommended that observation without antibiotics be the first line management option for at least 3 months for the child with OME (AAFP/AAOHNS/AAP, 2004 [S]). • It is recommended that all children with OME who have a positive assessment for pain be treated with an appropriate analgesic, though ear pain in OME is not common (AAP Subcommittee on Management of Acute Otitis Media, 2004 [S]; The assessment and management of acute pain, 2001 [S]). • It is recommended, for the otherwise healthy child

with persistent OME, that no medication be given (Williamson, 2002 [S]).

- It is recommended that the child with OME who is at risk for developmental difficulties (see table Risk Factors for Developmental Difficulties above) be aggressively managed as appropriate to his/her condition. This individualized management may include:
    - Earlier referral for audiologic evaluation (Friel-Patti & Finitzo, 1990 [C]; Carney & Moeller, 1998 [S])
    - Shorter intervals between visits
    - Antibiotic therapy
    - Referral for speech/language assessment
    - Referral for PE tubes, and/or
    - Referral for other otolaryngological evaluation

  Note: Preventive strategies may be helpful to children from special populations, from poor socioeconomic environments, or with development delays who are at risk for language and learning delay and who are experiencing hearing loss due to OME (Roberts et al., 2003 [M], 1998 [C], 1995 [C]; Roberts, Burchinel, & Zeisel, 2002 [C]). See Table 3 in the original guideline document.

- It is recommended that the otherwise healthy child with OME be evaluated at 1 to 2 months after diagnosis and then again at 3 months after diagnosis, or until either spontaneous, medical, or surgical resolution of the effusion is achieved or until basis for a referral is identified (Paradise et al., "Otitis media," 2003 [A], "Early versus delayed insertion," 2003 [A], 2001 [A]; AAFP/AAOHNS/AAP, 2004 [S]; Paradise, 2002 [X]).
- It is **not** recommended that other therapies be used in the treatment of OME.

  Systemic steroids, antihistamines, decongestants, and complementary or alternative treatments have not been documented to be efficacious in the treatment of OME, and some herbal preparations may have harmful side effects (Ernst, 2003 [M]; Mandel et al., 1987 [A]; Harrison, Fixsen, & Vickers, 1999 [B]; Fallon, 1997 [C]; Williamson, 2002 [S]; Miller et al., 2000 [S]).

  Note: It is recognized that use of CAM is common and its use is often not reported to the primary care physician (Eisenberg et al., 1998 [O]; Spigelblatt et al., 1994 [O]). The physician may take the OME visit

	as an opportunity to begin a respectful discussion regarding the safety and efficacy of CAM with families who report its use.
SIGN (2003)	**D** - Children with OME should not be treated with antibiotics. **B** - Decongestants, antihistamines, or mucolytics should not be used in the management of OME. **B** - The use of either topical or systemic steroid therapy is not recommended in the management of children with OME. **D** - Autoinflation may be of benefit in the management of some children with OME. Homeopathy. There is no evidence available to make any recommendations regarding the role of homeopathy in the management of OME. **A** - Children under three years of age with persistent bilateral OME and hearing loss of $\leq$25 dB, but no speech and language, development, or behavioural problems, can be safely managed with watchful waiting. If watchful waiting is being considered, the child should undergo audiometry to exclude a more serious degree of hearing loss.
Hearing Testing	
AAFP/AAOHNS/AAP (2004)	• **Hearing and Language:** Hearing testing is recommended when OME persists for 3 months or longer or at any time that language delay, learning problems, or a significant hearing loss is suspected in a child with OME; language testing should be conducted for children with hearing loss. (This recommendation is based on cohort studies and the preponderance of benefit over risk.) *Aggregate evidence quality: **B**, diagnostic studies with minor limitations; **C**, observational studies* *Policy level: **recommendation***
CCHMC (2004)	It is recommended that a child be referred for audiologic evaluation (see Table 4 in the original guideline document): • If OME persists for at least 3 months • If concerns are noted for hearing, speech, or

	language by parents, teachers, or healthcare providers, or • 3 months after a prior audiologic evaluation in a child being observed with OME (Johnston et al., 2004 [A]; Brody et al., 1999 [C]; Rosenfeld, Goldsmith, & Madell, 1998 [C]; AAFP/AAOHNS/AAP, 2004 [S]; Local Expert Consensus [E])
SIGN (2003)	**A** - Children under three years of age with persistent bilateral OME and hearing loss of $\leq$25 dB, but no speech and language, development, or behavioural problems, can be safely managed with watchful waiting. If watchful waiting is being considered, the child should undergo audiometry to exclude a more serious degree of hearing loss.
Referral To Subspecialists	
AAFP/AAOHNS/AAP (2004)	• **Referral**: When children with OME are referred by the primary care clinician for evaluation by an otolaryngologist, audiologist, or speech-language pathologist, the referring clinician should document the effusion duration and specific reason for referral (evaluation, surgery) and provide additional relevant information such as history of AOM and developmental status of the child. (This option is based on panel consensus and a preponderance of benefit over harm.) *Aggregate evidence quality: **C**, observational studies* *Policy level: **option*** See the original guideline document for additional detail about the minimum information that should be conveyed when making a referral.

CCHMC (2004)	• It is recommended that a child be referred for audiologic evaluation (see Table 4 in the original guideline document):
	  • If OME persists for at least 3 months
	  • If concerns are noted for hearing, speech, or language by parents, teachers, or healthcare providers, or
	  • 3 months after a prior audiologic evaluation in a child being observed with OME
	
	(Johnston et al., 2004 [A]; Brody et al., 1999 [C]; Rosenfeld, Goldsmith, & Madell, 1998 [C];

	AAFP/AAOHNS/AAP, 2004 [S]; Local Expert Consensus [E])
	
	• It is recommended that a child with MEE of at least 3 months duration be referred for evaluation for PE tube insertion for:
	  • Recurrent AOM (history of 6 episodes over a 12 month period taking into account the severity of episodes, clustering of episodes, and persistence of OME)
	  • Moderate hearing loss (see Table 4 in the original guideline document)
	  • Anatomic changes developing secondary to OME or AOM
	  • Clinical symptoms of severe retraction pockets in the tympanic membrane; otalgia; tinnitus; or if neurologic problems related to balance are evident
	  • Complications from AOM or chronic OME (such as mastoiditis, facial nerve paralysis, disturbance in balance, or meningitis) (Paradise et al., 2001 [A]; Engel-Yeger, Golz, & Parush, 2004 [C]; Paradise, 2002 [X]).
	• It is recommended that a child with MEE for at least 3 months duration with mild hearing loss (see Table 4 in the original guideline document) be considered for evaluation for PE tube insertion based upon risk factors (Teele, Klein, & Rosner, 1989 [C]) which may include:
	  • Developmental disorders (Shott, Joseph, & Heithaus, 2001 [C])
	  • Previous PE tubes
	  • Sibling history of ear infection
	  • Male gender
	  • Fall and winter season (Gordon, Grunstein, & Burton, 2004 [C])
	
	Note: The decision to refer earlier or later for evaluation for PE tube insertion rests on the advantages of avoiding surgery due to resolution of OME during the period of delay versus the added advantage the surgery provides by being performed sooner rather than later in the cases which do not resolve. The value placed on these uncertain variables by clinicians, combined with the patient biology and family preferences may result in different decisions for different patient:clinician dyads.
	
	• It is recommended that a child with signs of speech delay be referred for a speech and language

	evaluation (AAFP/AAOHNS/AAP, 2004 [S]). • It is recommended that appropriate and complete documentation, including what is expected from the specialist, accompany referrals to otolaryngologist, audiologist, or speech pathologist (Kuyvenhoven & De Melker, 1990 [D]; AAP Subcommittee on Management of Acute Otitis Media, 2004 [S]).
SIGN (2003)	**A** - Children under three years of age with persistent bilateral OME and hearing loss of $\leq$25 dB, but no speech and language, development or behavioural problems, can be safely managed with watchful waiting. If watchful waiting is being considered, the child should undergo audiometry to exclude a more serious degree of hearing loss. **B** - Children with persistent bilateral OME who are over three years of age or who have speech, language, developmental, or behavioural problems should be referred to an otolaryngologist.
Tympanostomy (PE) Tube Placement	
AAFP/AAOHNS/AAP (2004)	• When a child becomes a surgical candidate, tympanostomy tube insertion is the preferred initial procedure; adenoidectomy should not be performed unless a distinct indication exists (nasal obstruction, chronic adenoiditis). Repeat surgery consists of adenoidectomy plus myringotomy, with or without tube insertion. Tonsillectomy alone or myringotomy alone should not be used to treat OME. Surgical candidacy for OME largely depends on hearing status, associated symptoms, the child's developmental risk (see Table 3 in the original guideline document), and the anticipated chance of timely spontaneous resolution of the effusion. Candidates for surgery include children with OME lasting 4 months or longer with persistent hearing loss or other signs and symptoms, recurrent or persistent OME in children at risk regardless of hearing status, and OME and structural damage to the tympanic membrane or middle ear. Ultimately, the recommendation for surgery must be individualized based on consensus between the primary care physician, otolaryngologist, and parent or caregiver that a particular child would benefit from intervention. Children with OME of any duration who are at risk are candidates for surgery.

CCHMC (2004)	Evaluation for placement of PE tubes is the most common reason children with OME are referred to an otolaryngologist. The discussion of alternatives, risks, benefits, and expected outcomes associated with tube placement begins with the primary care clinician and is continued with the otolaryngologist if the patient is referred.
	
	• It is recommended that the child with OME who is at risk for developmental difficulties (see table Risk Factors for Developmental Difficulties above) be aggressively managed as appropriate to his/her condition. This individualized management may include:
	  • Earlier referral for audiologic evaluation (Friel-Patti & Finitzo, 1990 [C]; Carney & Moeller, 1998 [S])
	  • Shorter intervals between visits
	  • Antibiotic therapy
	  • Referral for speech/language assessment
	  • Referral for PE tubes, and/or
	  • Referral for other otolaryngological evaluation
	• It is recommended that an introduction and a discussion be initiated by the primary care clinician with the parents of children with documented OME of the procedure, alternatives, risks, benefits, and expected outcomes of PE tube insertion being considered for otolaryngological referral (Local Expert Consensus [E]).
	
	Note: It has been shown that insertion of tympanostomy tubes will reduce the total amount of time with effusions that a child will experience, but has not been shown to affect important speech/language development, behavior, or cognitive outcomes up to 4 years of age. Furthermore, prompt insertion of PE tubes (compared to delaying insertion 6 to 9 months) in otherwise healthy children with persistent (>3 months) OME in the first 3 years of life results in increased tympanic membrane (TM) abnormalities compared to children selectively managed; however, this finding is of questionable clinical significance (Johnston et al., 2004 [A]; Paradise et al, 2001 [A]).
	
	• It is recommended that a child with MEE of at least 3 months duration be referred for evaluation for PE tube insertion for:
	  • Recurrent AOM (history of 6 episodes over a 12 month period taking into account the severity of episodes, clustering of episodes,

	and persistence of OME) • Moderate hearing loss (see Table 4 in the original guideline document) • Anatomic changes developing secondary to OME or AOM • Clinical symptoms of severe retraction pockets in the tympanic membrane; otalgia; tinnitus; or if neurologic problems related to balance are evident • Complications from AOM or chronic OME (such as mastoiditis, facial nerve paralysis, disturbance in balance, or meningitis) (Paradise et al., 2001 [A]; Engel-Yeger, Golz, & Parush, 2004 [C]; Paradise, 2002 [X]). • It is recommended that a child with MEE for at least 3 months duration with mild hearing loss (see table entitled "Hearing Loss Definitions and Expected Auditory Behaviors in Children with OME" in original guideline) be considered for evaluation for PE tube insertion based upon risk factors (Teele, Klein, & Rosner, 1989 [C]) which may include: • Developmental disorders (Shott, Joseph, & Heithaus, 2001 [C]) • Previous PE tubes • Sibling history of ear infection • Male gender • Fall and winter season (Gordon, Grunstein, & Burton, 2004 [C]) Note: The decision to refer earlier or later for evaluation for PE tube insertion rests on the advantages of avoiding surgery due to resolution of OME during the period of delay versus the added advantage the surgery provides by being performed sooner rather than later in the cases which do not resolve. The value placed on these uncertain variables by clinicians, combined with the patient biology and family preferences may result in different decisions for different patient:clinician dyads.
SIGN (2003)	No recommendations offered. Discussion of surgical management is excluded from this guideline.

TABLE 3: BENEFITS AND HARMS	
Benefits	
AAFP/AAOHNS/AAP	• Pneumatic Otoscopy: improved diagnostic accuracy;

(2004)	inexpensive equipment • Tympanometry: increased diagnostic accuracy beyond pneumatic otoscopy; documentation • Screening: potentially improved developmental outcomes, which have not been demonstrated in the best current evidence • Documentation: defines severity, duration has prognostic value, facilitates future communication with other clinicians, supports appropriate timing of intervention, and, if consistently unilateral, may identify a problem with specific ear other than OME (e.g., retraction pocket or cholesteatoma). • Child at Risk: optimizing conditions for hearing, speech, and language; enabling children with special needs to reach their potential; avoiding limitations on the benefits of educational interventions because of hearing problems from OME. • Watchful Waiting: avoid unnecessary interventions, take advantage of favorable natural history, and avoid unnecessary referrals and evaluations • Medication: avoid side effects and reduce cost by not administering medications; avoid delays in definitive therapy caused by short-term improvement then relapse • Hearing and Language: to detect hearing loss and language delay and identify strategies or interventions to improve developmental outcomes • Surveillance: avoiding interventions that do not improve outcomes. • Referrals: better communication and improved decision-making • Surgery: improved hearing, reduced prevalence of OME, reduced incidence of AOM, and less need for additional tube insertion (after adenoidectomy) • Complementary and Alternative Medicine (CAM): not established • Allergy Management: not established
CCHMC (2004)	• Effective medical management of OME in children 2 months to 13 years of age • Improved identification of the at-risk child • Improved use of appropriate referral criteria • Improved parental involvement in decision-making around the management of OME
SIGN (2003)	• Improved diagnosis of OME • Improved management of OME • Improved use of appropriate referral criteria

Harms	
AAFP/AAOHNS/AAP (2004)	• Pneumatic Otoscopy: cost of training clinicians in pneumatic otoscopy • Tympanometry: acquisition cost, administrative burden, and recalibration • Screening: inaccurate diagnosis (false-positive or false-negative), overtreating self-limited disease, parental anxiety, cost of screening, and/or unnecessary treatment • Documentation: administrative burden • Child at Risk: cost, time, and specific risks of medications or surgery • Watchful Waiting: delays in therapy for OME that will not resolve with observation; prolongation of hearing loss • Medication: adverse effects of specific medications: side effects of antihistamines and decongestants include insomnia, hyperactivity, drowsiness, behavioral change, and blood-pressure variability; side effects of antimicrobials may include rashes, vomiting, diarrhea, allergic reactions, alteration of the child's nasopharyngeal flora, societal impact of antimicrobial therapy on bacterial resistance and transmission of resistant pathogens, and cost; oral steroids can produce behavioral changes, increased appetite, weight gain, adrenal suppression, fatal varicella infection, and avascular necrosis of the femoral head • Hearing and Language: parental anxiety, direct and indirect costs of assessment, and/or false-positive results • Surveillance: allowing structural abnormalities to develop in the tympanic membrane, underestimating the impact of hearing loss on a child, and/or failing to detect significant signs or symptoms that require intervention • Referrals: confidentiality concerns, administrative burden, and/or increased parent or caregiver anxiety • Surgery: risks of anesthesia and specific surgical procedures; sequelae of tympanostomy tubes • CAM: potentially significant depending on the intervention • Allergy Management: adverse effects and cost of medication, physician evaluation, elimination diets, and desensitization
CCHMC (2004)	None stated

SIGN (2003)	None stated

TABLE 4: EVIDENCE RATING SCHEMES AND REFERENCES	
AAFP/AAOHNS/AAP (2004)	**RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE** **Evidence Quality for Grades of Evidence** **Grade A**: Well-designed, randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population **Grade B**: Randomized, controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies **Grade C**: Observational studies (case-control and cohort design) **Grade D**: Expert opinion, case reports, or reasoning from first principles (bench research or animal studies) **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS** **Guideline Definitions for Evidence-Based Statements** **Strong Recommendation**: A strong recommendation means that the subcommittee believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B). In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. *Implication:* Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present. **Recommendation**: A recommendation means that the subcommittee believes that the benefits exceed the

	harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C). In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms. *Implication:* Clinicians also should generally follow a recommendation but should remain alert to new information and sensitive to patient preferences. **Option**: An option means that either the quality of evidence that exists is suspect (grade D) or that well-done studies (grade A, B, or C)* show little clear advantage to one approach versus another. *Implication:* Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set boundaries on alternatives; patient preference should have a substantial influencing role. **No Recommendation**: No recommendation means that there is both a lack of pertinent evidence (grade D) and an unclear balance between benefits and harms. *Implication:* Clinicians should feel little constraint in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.
CCHMC (2004)	**Evidence Based Grading Scale:** A: Randomized controlled trial: large sample B: Randomized controlled trial: small sample C: Prospective trial or large case series D: Retrospective analysis E: Expert opinion or consensus F: Basic laboratory research S: Review article M: Meta-analysis Q: Decision analysis L: Legal requirement O: Other evidence X: No evidence **References Supporting the Recommendations** American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery, American Academy of Pediatrics Subcommittee on Otitis Media with Effusion. Otitis media with effusion. Pediatrics

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SIGN (2003)	**Rating Scheme for the Strength of the Evidence** **Levels of Evidence** **1++** - High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very

	low risk of bias **1+** - Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias **1-** - Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias **2++** - High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal **2+** - Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal **2-** - Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal **3** - Non-analytic studies, e.g., case reports, case series **4** - Expert opinion **Rating Scheme for the Strength of the Recommendations** The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation. **Grade A**: At least one meta-analysis, systematic review of randomized controlled trials (RCTs), or randomized controlled trial rated as 1++ and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results **Grade B**: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+ **Grade C**: A body of evidence including studies rated as

	2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rate as 2++ **Grade D**: Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+ **Good Practice Points**: Recommended best practice based on the clinical experience of the guideline development group

GUIDELINE CONTENT COMPARISON

The American Academy of Family Physicians/American Academy of Otolaryngology-Head and Neck Surgery/American Academy of Pediatrics (AAFP/AAOHNS/AAP), Cincinnati Children's Hospital Medical Center (CCHMC) and Scottish Intercollegiate Guidelines Network (SIGN) present recommendations for diagnosis, management, and treatment of OME. All three guidelines provide explicit reasoning behind their judgments, ranking the level of evidence for each major recommendation. CCHMC also offers literature citations to support its major recommendations.

The guidelines differ somewhat in scope. The SIGN guideline addresses diagnosis and management of both AOM and OME. While all three guidelines address otitis media (OM) in children only, AAFP/AAOHNS/AAP and CCHMC target children 2 months and older, SIGN does not specify an age range, but targets children in general. AAFP/AAOHNS/AAP and CCHMC address the consideration of PE tubes, while SIGN explicitly excludes discussion of this topic. AAFP/AAOHNS/AAP also addresses research needs related to OME.

Areas of Agreement

Diagnosis

Diagnostic Otoscopy

The three guidelines agree that otoscopy should be used to determine if MEE is present and they are in general agreement that pneumatic otoscopy is preferable to simple otoscopy. AAFP/AAOHNS/AAP and CCHMC cite research showing that pneumatic otoscopy has higher diagnostic sensitivity and specificity than simple otoscopy. While agreeing that pneumatic otoscopy offers better sensitivity, SIGN makes no formal recommendation concerning which technique to use; it notes that pneumatic otoscopy is not widely used in the primary care setting in the United Kingdom and that, were it to become routinely used, practitioners would require training in its use.

Adjunctive Diagnostic Techniques

All three guidelines agree that tympanometry is a useful adjunct to otoscopy for diagnosing OME. SIGN notes, however, that tympanometry is rarely used in the primary care setting in the United Kingdom, and that the GP will have to depend on history and otoscopy for diagnosing OM.

AAFP/AAOHNS/AAP and CCMHC further agree that acoustic reflectometry is a useful adjunctive technique, although CCMHC observes that it is not often used nor readily available in the Cincinnati area. The SIGN guideline does not address use of acoustic reflectometry.

Management

Watchful Waiting

There is general agreement among the guidelines that the majority of OME cases resolve spontaneously within a few weeks. AAFP/AAOHNS/AAP and CCHMC explicitly recommend that OME be managed by watchful waiting for 3 months. SIGN makes the recommendation that children under three years of age who are not at risk for speech, language, development, or behavioral problems can be safely managed with watchful waiting, but does not specify the time period for observation.

Medication

Antibiotics. The three guidelines are in agreement that antibiotics should not be used to treat most cases of OME, with all observing that the existing research shows short-term but not long-term benefit from the use of antibiotics for routine treatment of OME. AAFP/AAOHNS/AAP, CCHMC, and SIGN recommend against the use of antibiotics for OME in otherwise healthy children, though CCHMC does include antibiotic therapy as an option for aggressive individual management of children with OME who are at risk for developmental difficulties.

Other Medications. The three guidelines are in agreement that decongestants and antihistamines should not be used in the management of OME, with AAFP/AAOHNS/AAP and SIGN noting they have not been shown to be beneficial and are associated with potential adverse side effects. All three guidelines recommend against the use of systemic steroids, citing lack of evidence of long-term benefit. Additionally, AAFP/AAOHNS/AAP and SIGN observe there is no evidence that nasal steroids are associated with improved outcomes.

Children at Risk

There is agreement among the guidelines that children at risk for hearing, speech and language, and/or developmental problems should be identified early and managed aggressively, including early referral for hearing, speech, and language assessment and evaluation by an otolaryngologist.

Hearing Testing

The guidelines generally agree in their recommendations concerning the need for hearing testing. For uncomplicated OME, AAFP/AAOHNS/AAP and CCHMC recommend hearing testing when OME persists for 3 months or longer; CCHMC further recommends hearing testing 3 months following initial audiologic evaluation in the child being observed with OME. SIGN recommends audiometry for children under 3 years of age with persistent bilateral OME and mild to moderate hearing loss ($\leq$25 dB) who are otherwise healthy (to exclude a more serious degree of hearing loss).

All of the guidelines recommend prompt hearing testing when language delay, learning problems, and/or a significant hearing loss is suspected in a child with OME, regardless of the duration of OME.

PE Tube Insertion

The guidelines agree that early referral to an otolaryngologist is warranted for children at risk for hearing, speech and language, or developmental delays; children with anatomical abnormalities (such as cleft palate, bifid uvula, and Down syndrome); and children with clinical complications of OME. They also agree that PE tube insertion is the surgical intervention of choice, though AAFP/AAOHNS/AAP also considers adenoidectomy. Further, AAFP/AAOHNS/AAP and CCHMC generally recommend surgical evaluation for children with OME lasting 3 or 4 months with hearing loss or other complications. SIGN, while agreeing with the other guidelines concerning the need for early referral of at-risk children to an otolaryngologist, explicitly excludes the topic of PE tubes from its guideline.

Areas of Differences

As discussed above, while all three guidelines recommend against the routine use of antibiotics for OME, CCHMC includes exceptions for which antibiotic use may be warranted CCHMC includes antibiotic therapy as an option for aggressive individualized management of the child with OME who is at risk for developmental difficulties.

Although not a specific focus of this guideline synthesis, one other important difference between the guidelines included in this synthesis relates to CCHMC's emphasis on the involvement of parents in the discussion and decision of the management options. Likewise, although not a focus of their guideline, AAP also presents recommendations for the involvement of parents in the decision-making process. SIGN does not address this specific topic.

There are no other key areas in which the three guidelines differ substantially in their recommendations.

This Synthesis was prepared by ECRI on February 13, 2006. The information was verified by AAP on March 6, 2006, and by CCHMC and UMHS on March 20, 2006. This synthesis was updated on December 6, 2007 to remove recommendations from UMHS.

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